

does not change the same indivisible nature of the invention described in each of the claims of the present invention. Because the present composition claims relate to the same indivisible invention of a non-emulsion topical gel composition, Applicants request that the constructive election of species (b) directed to sterol-based surfactant/emulsifier in Claims 1 to 3, 7 to 19, 21, 23, 25 and 26 be withdrawn and the subsequent withdrawal of Claims 4 to 6, 20, 22, and 24 be reversed.

II. The Examiner's 112 Rejections

The Examiner alleges that Claims 1 to 3, 7, 9 to 19, 23, 25 and 26 fail to particularly point out and distinctly claim the subject matter of the present invention for a number of reasons each of which is addressed primarily in the order of appearance in the office action. First, Claims 1, 7, 15 and 16 contain terms, "carbohydrate-based" and "sterol-based," and according to the Examiner, render the metes and bounds of the claims indeterminable. However, Applicants refer to page 4 of the specification, wherein at lines 5 to 6, sterol-based surfactants are described as including cholesterol, phytosterols, or derivatives thereof. "An applicant has a right to define what he regards as his invention as he chooses, so long as his definition is reasonably distinct, and supported by an enabling disclosure, as required by the first paragraph of 35 U.S.C. 112." *Ex parte Ohsumi*, 21 USPQ2d 1020, 1024 (BdPatApp&Int 1991)(Markush claim is employed when there is no commonly accepted generic expression commensurate in scope with the field covered); see *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980). One of ordinary skill in the art understands what "sterol-based" means as its meaning is commonly known and it is supported by the present specification, and therefore, Applicants request that these rejections be withdrawn.

Second, according to the Examiner, Claims 1, 15 and 16 include the term "substantially" which is not defined by the claims or the specification, and therefore, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. In addition, Claims 1 to 3, 7, 9 to 19, 23, 25 and 26 are also rejected by the Examiner for being indefinite because they recite "substantially no oil." However, Applicants direct attention to page 4, lines 16 to 20, wherein the meaning of "substantially no oil" is described. It states "[t]he composition of the invention contains substantially no oil, by which is meant there is less than about 5%, preferably less than about 3%, so as to avoid the creation of an emulsion, which may alter the desirable mousse texture." As provided in MPEP 2173.05(b), recognition is given to the fact that the term "substantially" is often used. Further, it sets forth the conditions under which use of the term "substantially" in a claim meets the definiteness requirement. A claim is definite when "substantially" is viewed in light of the guidelines provided in the specification, and when one of ordinary skill in the art would know what is meant by "substantially". See *In re Mattison*, 509 F.2d 563,

184 USPQ 484 (CCPA 1975); *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988). The term “substantially” in the present claims is supported by the specification and one of ordinary skill in the art would know what is meant by substantially, and therefore, Applicants request that these rejections be withdrawn.

Third, the Examiner finds that there is lack of antecedent basis for “amine” in Claim 2. In addition, the Examiner finds Claims 15 and 16 to be indefinite because it is unclear whether an amine or an amine salt of a fatty acid is claimed. Claims 1, 2, 15, and 16 have been amended according to the Examiner’s suggestion for clarity. In addition, the Examiner finds that Claims 9 and 23 recite an additional limitation that is not recited in the parent claims but are confusing. Applicants amend these two claims according to the Examiner’s suggestion for clarity. Claim 10, according the Examiner, is uncertain as to whether the colors in parentheses are required limitations. Applicants amend the claims for clarity. As amended, the claims are believed to meet the requirements of 35 U.S.C. §112, second paragraph, and therefore, Applicants request that these rejections be withdrawn.

III. The Examiner’s Rejections under 35 U.S.C. §102(b)

Claims 1, 2, 7 to 11, and 14 are rejected under 35 U.S.C. §102(b) as being anticipated by McEleney et al. (U.S. Pat. No. 5,567,420, hereinafter referred to as “the ‘420 reference”) and separately, the same claims are rejected as being anticipated by Tominaga (U.S. Pat. No. 5,747,049, “the ‘049 reference”). However, neither reference discloses a non-emulsion gel composition. A rejection for anticipation or lack of novelty requires that all the elements of the claimed invention be described in a single reference. *In re Spada*, 15 USPQ2d 1655, 1657 (CAFC 1990) (citing *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir.), cert. den., 110 S.Ct. 154 (1989)). Prior art does not anticipate if it does not contain each and every limitation of the claims. *Union Oil Co. of California v. Atlantic Richfield Co.*, 54 USPQ2d 1227, 1232 (CAFC 2000); See *Verdegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1052-53 (Fed. Cir. 1987)(broader classes of fuel excluded from the narrow claim limitation of a standard automotive fuel composition). The present invention, as amended, is a non-emulsion gel-type composition. Specifically, as set forth in the present specification at page 2, lines 27 to 28, the base of the composition is a polyhydric alcohol gelled by an amine or an alkali metal salt of a fatty acid ester, and the other component of the composition is a carbohydrate-based or sterol-based surfactant/emulsifier. The compositions of the present invention contain substantially no oil, feel non-oily and are easy-to-use.

As disclosed in the '049 reference, the compositions can be in the form of a gel, however, the '049 reference fails to disclose the components of the non-emulsion topical gel of the present invention as they are arranged in the claims. Anticipation requires "the presence in a single prior art disclosure of all elements of a claimed invention arranged as in that claim." *Carella v. Starlight Archery*, 231 USPQ 644, 646 (CAFC 1986) (citing *Panduit Corp. v. Dennison Manufacturing Co.*, 774 F.2d 1082, 1101, 227 USPQ 337, 350 (Fed. Cir. 1985); *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983)). In fact, there are no components of such a gel disclosed in the '049 reference. Therefore, one of ordinary skill in the art would not recognize the present invention by the '049 disclosure and the present invention is not anticipated by it. Under 35 U.S.C. §102, every limitation of a claim must identically be disclosed in a single prior art reference for it to anticipate the claim. *In re Bond*, 910 F.2d 831, 832, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990); see *Gechter v. Davidson*, 43 USPQ2d 1030, 1032 (CAFC 1997). The disclosure need not be express, but may anticipate by inherency such that it would be appreciated by one of ordinary skill in the art. *Glaxo Inc. v. Novopharm Ltd.*, 34 USPQ2d 1565, 1567 (CAFC 1995)(citing *Continental Can Co. USA Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991)). The '049 reference fails to expressly disclose the details of any type of gel let alone the non-emulsion gel of the present invention which comprises specific components. Therefore, one of ordinary skill in the art would not be able to make a non-emulsion gel based on the disclosure of the '049 reference, and the '049 reference fails to render the present invention unpatentable on the basis of anticipation.

The Examiner also asserts that the '420 reference discloses all of the limitations of the present invention. Like the '049 reference, however, the '420 reference discloses an emulsion at column 3, lines 34 to 36, wherein the '420 color indicator is dispersed in an emulsion of sunscreen or lotion. The emulsion can also be in the form of a gel, as disclosed at lines 36 to 38. However, at column 3, lines 38 to 40, when water and propylene glycol are present they are disclosed specifically in the '420 reference in an emulsion. Therefore, the '420 reference fails to disclose the present invention of a water-containing non-emulsion as described in the claims of the present invention. Further, neither of these cited references inherently discloses a non-emulsion gel-type composition. As both of the cited references fail to disclose the present invention, Applicants request that the rejections based on 35 U.S.C. §102(b) be withdrawn.

IV. The Examiner's Rejection under 35 U.S.C. §103

In the present Office Action, Claims 1, 2, 7 to 11, 14 to 17, 21, 23, and 25 are rejected under 35 U.S.C. §103 as being unpatentable over either U.S. Patent No. 5,567,420 issued to McEleney et al. ("the '420 reference") or U.S. Patent No. 5,747,049 issued to Tominaga ("the '049 reference"). The Examiner notes, however, that although they each do not teach the amounts of the components as claimed in Claims 15 and 16, the ability to select optimal amounts are within the skill of the art to achieve a beneficial effect. As indicated, above with respect to the Examiner's §102 rejections, each of the cited references not only fails to teach the amounts, but moreover, fails to teach a non-emulsion gel. The '049 reference teaches a treatment for suppressing collagen cross-linking by applying an aminoethyl compound and includes the form of an aqueous solution as taught at column 7, line 37. However, non-emulsion gels are not taught or suggested by the '049 reference, and thus, the Examiner fails to make a *prima facie* case of obviousness. *In re Geisler*, 43 USPQ2d 1362, 1365 (CAFC 1997). The '049 reference merely lists literally hundreds of different components in isolation without any teaching of how they are to be combined let alone how they could be combined to achieve a mousse-like gel of the present invention. In the absence of the claimed invention from the prior art, if there is simply no basis upon which to predicate what seems to be the most unlikely combination in the prior art, obviousness is not found. *In re Schoenewaldt*, 145 USPQ 289, 292 (CCPA 1965) (references including a shot gun disclosure fail to give any indication of either the utility or the properties of the claimed compound except as properties were attributable to them by hindsight).

The present invention is a non-emulsion gel which is unexpectedly moisturizing and feels cool. In Claims 15 and 16, for example, of water is 20 to 60%. However, in light of the teachings and suggestions of the '049 reference, at column 6, lines 22 to 34, moisturization is achieved by adding a humectant, therefore, the '049 reference fails to recognize the benefits of the non-emulsion gel of the present invention using just water. Even if a *prima facie* case of obviousness could be made, it is rebutted by the unexpected properties of the present invention, i.e., showing that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected." *In re Geisler*, 43 USPQ2d 1362, 1365 (CAFC 1997); see *In re Soni*, 54 F.3d 746, 750, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995).

In addition, the Examiner finds that the '420 reference renders the present invention obvious because it teaches all of the limitations of the claims of the present invention. As demonstrated above with respect to the §102 rejection, the presence of water in the '420 compositions is associated with emulsions. Therefore, the '420 reference fails to teach or suggest a non-emulsion gel. However, like the

'049 reference, the '420 reference also fails to teach or suggest a non-emulsion containing 20 to 60% water, as described in the claims of the present invention. Further, although both the '049 reference and the '420 reference disclose a variety of additional ingredients that can be added to their compositions, neither reference teaches or suggests the present invention or the beneficial effect achieved with a non-emulsion gel composition containing water and substantially no oil. These unexpected benefits of the present invention are not even recognized by the cited references.

The Examiner further cites several other patents in combination with either the '420 and the '049 references ("the primary references") against Claims 1, 2, 7 to 11, 14 to 17, 21, 23, and 25. First, U.S. Patent No. 5,424,070 ("the '070 reference") is cited by the Examiner in combination with either of the primary references. The '070 reference teaches a clear transparent solid stick, and thus, fails to disclose the non-emulsion gel of the present invention. Thus, the '070 reference fails to remedy the defects of the '420 and the '049 references. However, the Examiner relies on the '070 reference as teaching the equivalence of sodium behenate and sodium stearate in topical composition. "It is impermissible within the framework of §103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art". *In re Hedges*, 228 USPQ 685, 687 (CAFC 1986)(citing *In re Wesslau*, 353 F.2d 238, 241, 147 USPQ 391, 393 (CCPA 1965) (the reference is considered in its entirety for what it fairly suggests to one skilled in the art)). There is no teaching or suggestion of using sodium behenate as a single component in the '499 reference, nevertheless, as a gelling agent in a non-emulsion gel which also comprises a surfactant/emulsifying system. Further, the use of sodium behenate and sodium stearate in a stick composition is not motivation to use these compounds in the compositions of either the '420 reference or the '049 reference to achieve the non-emulsion gel of the present invention, since the purpose of the present invention is to produce a soft gel and not a solid stick. Thus, there is no motivation to combine the '070 reference with either the '420 reference or the '049 reference to make the present invention. In the absence of some teaching or suggestion to support the combination of prior art references, obviousness cannot be established by their combination to produce the claimed invention. *In re Bell*, 26 USPQ2d 1529, 1531 (CAFC 1993) (citing *Fine*, 837 F.2d at 1075, 5 USPQ2d at 1598).

The Examiner also cites U.S. Patent No. 5,741,499 ("the '499 reference") in combination with either of the references. The '499 reference teaches a composition comprising an organofluorinated hydrocarbon with at least one hydrocarbon glycol as an alternative to surfactants. The use of a

hydrocarbon glycol and an organofluorinated hydrocarbon in the compositions of either the '420 reference or the '049 reference does not teach or suggest the present invention which uses a carbohydrate-based or sterol-based surfactant or emulsifier to achieve a soft gel. The gelling agent of the present invention is solubilized in a polyhydric alcohol. Thus, because the '499 reference teaches that its compositions are an alternative to surfactants, the '499 reference teaches away from the present invention which includes a surfactant/emulsifier and a polyhydric alcohol as part of its non-emulsion gel. If the "the totality of the prior art disclosures leads substantially away from the claimed invention", obviousness is not found. *In re Hedges*, 228 USPQ 685, 687 (CAFC 1986). Therefore, the combination of these cited references fails to render the present invention obvious.

Finally, the Examiner cites U.S. Patent No. 5,393,526 ("the '526 reference") also in combination with either of the primary references. The Examiner finds that the '526 reference teaches compositions that generally require pigments and preferably, dimethicone coated titanium dioxide. The '526 reference teaches compositions that contain $C_2 - C_{28}$ α -hydroxy carboxylate, rosmarrinic acid and a carrier to reduce stinging and irritation associated with $C_2 - C_{28}$ α -hydroxy carboxylates. Thus, as the '526 reference fails to remedy the defects of the '049 or the '420 reference in that the '526 reference, like all of the cited references, fails to teach or suggest a non-emulsion gel composition, the combination of these references fails to render the present invention obvious.

The present invention is a substantially oil-free cosmetic composition with excellent moisturizing properties. In affirming the decision of the lower district court, the Court of Appeals noted that while any invention can be expected to consist of a combination of old elements, it is the claimed combination that must be found obvious to render the invention unpatentable. *The Gillette Co. v. S.C. Johnson & Son Inc.*, 16 USPQ2d 1923, 1927 (CAFC 1990). The critical inquiry is whether "there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination." *The Gillette Co. v. S.C. Johnson & Son Inc.*, 12 USPQ2d 1929, 1945 (DC Mass) (citing *Lindemann Maschinenfabrik v. American Hoist & Derrick*, 730 F.2d 1452, 1462, 221 USPQ 481, 488 (Fed. Cir., 1984)). The compositions of the present invention are non-emulsion gel compositions comprising an aliphatic polyhydric alcohol, a gelling agent of an alkali salt or an amine salt of a fatty acid, a surfactant/emulsifier, water, and substantially no oil. The cited references at best describe the critical components of the invention entirely in isolation, and lack any teaching, suggestion or motivation to combine them in any particular way. Therefore, because none of the cited references discloses a non-emulsion gel composition, and because none of the cited references discloses the unexpected benefits of

a non-emulsion gel composition, a *prima facie* case of obviousness has not been made, and Applicants request that the Examiner's rejection under 35 U.S.C. §103 be withdrawn.

MISCELLANEOUS

The Examiner asserts that a new oath or declaration is required because the present Declaration does not identify the post office address of each inventor. However, the Declaration submitted with the present application on November 17, 1999 on page 1 states that "[m]y residence, [and] post office address . . . are as stated below next to my names and on page 3 includes 1) the home address in the box entitled "Residence", and includes the city, state and zip code in the box entitled "Residence". According to the Examiner, the post office address may be a home address and should include the zip code. Therefore, because this requisite information is supplied in the Declaration in accordance with the provisions of 37 CFR 1.63(a)(3), Applicants respectfully request that the Examiner's objection be withdrawn.

CONCLUSION

In view of the arguments presented above in the present submission, the claims are believed to be in condition for allowance, and issuance of a Notice of Allowance is respectfully solicited.

Respectfully submitted,

Date: 7/13/01

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MARKED AMENDMENTS

1. (Amended) A non-emulsion topical gel composition comprising an aliphatic polyhydric alcohol, an alkali salt of a fatty acid ester or an amine salt of a fatty acid ester, a carbohydrate-based or sterol-based surfactant/emulsifier or combination thereof, water, and substantially no oil.
2. (Amended) The composition of claim 1 in which the alkali salt is a sodium[,] or potassium or amine salt of a C12-C22 fatty acid.
9. (Amended) The composition of claim 1 which further contains at least one pigment.
10. (Amended) The composition of claim 9 in which the pigment is selected from the group consisting of iron oxides [(yellow, red, brown or black)], ferric ammonium ferrocyanide[(blue)], manganese violet, ultramarine blue, chrome oxide[(green)], talc, zeolite, kaolin, titanium dioxide[(white)], zinc oxide, and mixtures thereof.
15. (Amended) A non-emulsion, topical gel composition comprising
 - (a) from about 10 to about 40% of an aliphatic polyhydric alcohol;
 - (b) from about 1 to about 15% of an amine salt of a fatty acid or an alkali metal salt of a fatty acid;
 - (c) from about 1 to about 10% of a sterol- or carbohydrate-based surfactant/emulsifier[.];
 - (d) from about 20 to about 60% of water[.];the composition containing substantially on oil.
16. (Amended) The composition of claim 15 comprising
 - (a) from about 10 to about 25 % of an aliphatic polyhydric alcohol;
 - (b) from about 1 to about 6% of an amine salt of a fatty acid or an alkali metal salt of a fatty acid;
 - (c) from about 2 to about 6% of a sterol- or carbohydrate-based surfactant;
 - (d) from about 20 to about 60% of water[.];the composition containing substantially no oil.